(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
24 October 2002 (24.10.2002)

PCT

(10) International Publication Number
WO 02/083234 A1

(51) International Patent Classification[7]: A61N 1/05

(21) International Application Number: PCT/SE02/00602

(22) International Filing Date: 25 March 2002 (25.03.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0101340-8 12 April 2001 (12.04.2001) SE

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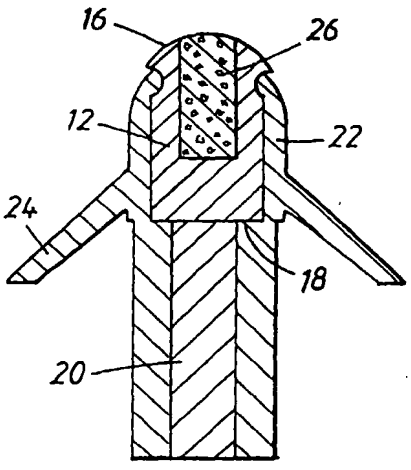
(81) Designated State *(national)*: US.

(84) Designated States *(regional)*: European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: AN ELECTRICALLY CONDUCTIVE LEAD AND A METHOD OF PRODUCING SUCH A LEAD



(57) Abstract: The invention concerns an electrically conductive lead suitable to be implanted in a human or animal body. The lead comprises a proximal end portion designed to be attached to a device and a distal end portion comprising at least one electrode member (12) for emitting and/or sensing electrical signals. The lead also has an elongated body extending between the proximal end portion and the distal end portion. According to the invention, at least a part (26) of said electrode member (12) is formed of a porous metal foam material. The invention also concerns a method of producing such a lead.

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An electrically conductive lead and a method of producing such a lead

BACKGROUND OF THE INVENTION

1. Field of the invention

The present invention relates to leads which are electrically conductive and which are suitable to be implanted in a human or animal body. Such leads may for example be used to conduct electrical stimulation pulses from an implanted heart stimulating device to the heart of said human or animal body. Leads may, however, also be used in connection with other kinds of medical devices. Preferably the heart electrode leads are adapted to be insertable via the vascular system into the human or animal heart. Such heart electrode leads are particularly suitable for intracardial stimulation of the heart with the help of an implantable pacemaker or defibrillator. The invention concerns both a lead as such and a method of producing a lead.

1. Description of the prior art

A large number of different leads are known in the art. A lead normally has a proximal end portion to be connected to a device, for example a heart-stimulating device, and a distal end portion that is to be positioned at a predetermined position in the body, usually in or at the heart. A heart electrode lead may be unipolar or bipolar. A unipolar lead has only one single electrode member usually arranged at the tip of the distal end portion of the lead. A bipolar lead has two electric poles. Also this kind of electrode lead usually has one electrode member located at the tip at the distal end portion of the lead. The lead has at least one electric conductor, which extends from the proximal end portion to the electrode member at the distal end portion.

The electrode members may be formed in different materials and may have different configurations. In some leads a drug is arranged at the distal end portion of the lead. The drug is arranged such that it will be dispensed to the surrounding body tissue over a period of time after the lead has been implanted into the body. Without such a drug, the stimulation threshold has a tendency to be relatively high during a certain time after the implantation.

US-A-5 103 837 describes that a coating including a drug is provided on an electrode member of titanium nitride.

US-A-4 819 661 describes different leads with helical fixation members. A drug impregnated matrix, preferably of a biocompatible silicon adhesive, is positioned in a cavity at the distal end portion of the lead. The document describes that a drug impregnated matrix in a viscous or malleable state may be injected into a cavity whereafter the matrix cures and solidifies.

US-A-5 003 992 also describes a lead with a helical fixation member. A plug made of a polymer with a drug is located in a cavity at the distal end portion of the lead.

US-A-4 506 680 describes a lead including an electrode member located at the distal end of a lead. The electrode member includes a sintered porous metal elution path. In a cavity inside of this elusion path a polymer impregnated with a drug is positioned. The document also mentions that a drug may additionally be applied to a porous portion of the tip electrode, adjacent the exit point of the elution path.

US-A-4 577 642 describes a lead with a porous sintered metal electrode member located at the distal end of the lead. In a cavity inside of the electrode member, a drug is retained in a solid plug or a powder wherein the drug is compounded with an appropriate molecular sieve material. The drug is dispensed through an elution path within the electrode member. The document also mentions that

a drug may additionally be applied to a porous portion of the tip electrode, adjacent the exit point of the elution path.

The article "Fibrous tissue ingrowth and attachment to porous tantalum" by S. A. Hacking et al, J Biomed Mater Res, 52, 631-638, 2000, describes the formation of a tantalum foam material by forming a thermosetting polymer foam precursor in order to obtain a foam skeleton comprising a dodecahedron array or pores and then depositing tantalum onto this skeleton. The article reports a study of fibrous tissue ingrowth and attachment to such porous tantalum.

SUMMARY OF THE INVENTION

One object of the present invention is to provide a lead which enables an efficient transfer of electrical signals between an electrode member and the surrounding tissue. A second object is to provide a method of producing such a lead.

Further advantages of the invention will become clear from the following description.

The first object is achieved by an electrically conductive lead suitable to be implanted in a human or animal body, the lead comprising:

a proximal end portion designed to be attached to a device,

a distal end portion comprising at least one electrode member for emitting and/or sensing electrical signals,

an elongated body extending between said proximal end portion and said distal end portion,

wherein at least a part of said electrode member is formed of a porous metal foam material.

Since the electrode member comprises a metal foam material member, the electrode member may be formed with a high porosity. This means that the total surface area of the electrode member will be high. Through this feature, a very good electrical contact

between the electrode member and the surrounding body tissue or body fluids is achieved when the lead has been implanted into the body. Furthermore, a metal foam material is relatively easy to produce. An advantageous lead may thus be obtained in a relatively simple manner.

According to a preferred embodiment of the invention, a drug adapted to be released into said human or animal body is arranged in said porous part. Since the electrode member is formed by a metal foam material it is easy to locate a drug in the electrode member. Such a drug will be released into the surrounding body tissue after the lead has been implanted into the body. The advantages with such a drug release may thus be obtained in an advantageous and efficient manner according to the present invention.

According to a further embodiment, said drug comprises an anti-inflammatory agent. Such a drug may, for example, be used to decrease the stimulation threshold after that a heart electrode lead has been implanted into the body.

According to a still further embodiment, said electrode member is positioned at the distal end tip of the lead such that the distal end tip of the lead is formed by said porous metal foam material. By this feature, the part of the electrode lead that is in direct contact with the surrounding body tissue is formed by the advantageous porous metal foam material.

According to a further preferred embodiment, substantially the whole electrode member is formed of said porous metal foam material. The whole electrode member may thus be formed in one and the same material. Furthermore, since the whole electrode member is formed by the porous metal foam material, a relatively large amount of drug may be included in the electrode member. Moreover, the electrode member will have a large surface area in contact with the surrounding body tissue or fluids.

According to a further embodiment, the material of said electrode member comprises tantalum and/or titanium. Such materials are advantageous to be used for electrode members. Furthermore, such materials may be relatively easily formed as metal foams.

According to a still further embodiment, the pores of said part, which is formed of a porous metal foam material, constitute at least 50% of the volume of said part. Through this feature, a relatively large amount of drug may be arranged in the electrode member. For optional ingrowth, the size of the pores should be 30-200 μm.

The second object of the invention is achieved by a method of producing an electrically conductive lead suitable to be implanted in a human or animal body, the method comprising:

providing an electrode member wherein at least a part of said electrode member is formed of a porous metal foam material,

providing other members for forming the lead and assembling the members to form an electrically conductive lead having a proximal end portion designed to be attached to a device, a distal end portion, which comprises said electrode member, the electrode member being arranged for emitting and/or sensing electrical signals, and an elongated body extending between said proximal end portion and said distal end portion.

Through this method a lead having the advantages described above is produced.

Different preferred manners of carrying out the method are defined in the claims 9-14. The advantages of these manners of carrying out the method are already clear from the above description in connection with the different embodiments of the lead.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig 1 shows a schematic side view of a distal portion of a lead according to the prior art.

Fig 2 shows a schematic side view of a proximal portion of a lead according to the prior art.

Fig 3 shows a sectional view of a distal end portion of a lead according to the prior art.

Fig 4 shows a schematic sectional view of a distal end portion of a lead according to an embodiment of the present invention.

Fig 5 shows the same view as Fig 4 of another embodiment of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Fig 1-3 show different views of a lead according to the prior art. However, the general configuration of the lead according to the present invention may be the same as that of the prior art.

The lead has a proximal end portion (Fig 2) with connecting means 10 designed to be attached to a device, for example to an implantable heart stimulating device. Furthermore, the lead has a distal end portion (Fig 1) comprising an electrode member 12 for emitting and/or sensing electrical signals. The shown lead is bipolar and thus has a further electrode member 14. The lead has an elongated body extending between said proximal end portion and said distal end portion, i.e. the elongated body connects the two parts of the lead shown in Fig 1 and Fig 2.

Fig 3 shows a sectional view of the distal end portion of the lead. Fig 3 shows that the electrode member 12 has a first surface portion 16 with a smooth curvature facing the exterior of the distal

end portion and a second surface portion 18 facing the interior of the lead. The lead has at least one electric conductor 20 extending between the electrode member 12 and the connecting means 10. The lead also has at least one insulating member 22, for example made of silicon rubber, which encloses the electric conductor 20. The distal end portion of the lead may be provided with tines 24 to facilitate the anchoring of the electrode tip at the body tissue.

As already mentioned above, the general configuration of a lead according to the present invention may be the same as according to the prior art as has been described above in connection with Fig. 1-3. The same reference numerals are used for the corresponding parts in the different figures. Preferably, the lead of the invention is designed such that it may be inserted into a human or animal heart via the vascular system.

Fig. 4 shows a schematic sectional view of the distal end portion of a lead according to the invention. Fig. 4 thus shows an electrode member 12. The electrode member 12 may have different shapes and the present invention is thus not limited to a particular shape of the electrode member 12. However, according to present invention at least a part 26 of the electrode member 12 is formed of a porous metal foam material. According to the embodiment shown in Fig 4, the electrode member 12 is positioned at the distal end tip of the lead such that the distal end tip of the lead is formed by said porous metal foam material.

According to the embodiment shown in Fig 5, substantially the whole electrode member 12 at the distal end tip of the lead is formed by the porous metal foam material.

The electrode member 12 may be formed of any suitable electrically conductive material, for example tantalum, titanium, platinum or alloys based on these materials. The size of the pores in the metal foam material and the portion of the total volume of the electrode member 12 that is formed by the pores may be decided depending of the particular intended use of the electrode member 12. The

pores of the metal foam material may for example constitute at least 50 % of the volume of the part 26 formed by the metal foam material. In order to further increase the surface area of the electrode member 12, the electrode member 12 may be provided with a suitable coating, for example comprising titanium nitride.

Preferably, a drug is arranged in the porous part 26. The drug may comprise an anti-inflammatory agent, such as a steroid, for example dexamethasone sodium phosphate.

The drug may be maintained in the metal foam electrode member 12, 26 by being included in any suitable material. Such material may for example be degradable or non-degradable. As examples of degradable materials, the following can be mentioned: PLA (polylactic acid), PGA (polyglycollic acid) and PDS (polydioxanone). Examples of non-degradable materials are PEG (polyethylene glycol) and PVP (polyvinylpyrrolidone). According to one embodiment the material may be in the form of a gel.

According to the method of the invention, an electrode member 12 is provided, wherein at least a part 26 of the electrode member 12 is formed of a porous metal foam material. Examples of such materials are given above. Metal foam materials may be formed in different manners and any suitable manner may be used for the present invention. The metal foam material may for example be formed in the manner described in the above-mentioned article by S. A. Hacking et al.

Furthermore, according to the method, the other members necessary for forming the lead are provided and the members are assembled to form an electrically conductive lead having a proximal end portion designed to be attached to a device, a distal end portion, which comprises the electrode member 12, wherein the electrode member 12 is arranged for emitting and/or sensing electrical signals. The lead is formed to include an elongated body extending between the proximal end portion and the distal end portion.

According to a preferred embodiment of the method, a drug is arranged in the porous part 26 of the electrode member 12. Examples of suitable drugs and suitable materials in which the drug may be included have already been described above.

The invention is not limited to the above described embodiments, but may be varied within the scope of the following claims. For example, in addition to the drug arranged in the porous metal foam material, the electrode lead may comprise a cavity located inside of the electrode member 12, in which cavity a further amount of drug is included. The drug included in such a cavity may be used for long term release through the porous part of the electrode member 12.

Claims

1. An electrically conductive lead suitable to be implanted in a human or animal body, the lead comprising:

a proximal end portion designed to be attached to a device,

a distal end portion comprising at least one electrode member (12) for emitting and/or sensing electrical signals,

an elongated body extending between said proximal end portion and said distal end portion,

wherein at least a part (26) of said electrode member (12) is formed of a porous metal foam material.

2. An electrically conductive lead according to claim 1, wherein a drug adapted to be released into said human or animal body is arranged in said porous part (26).

3. An electrically conductive lead according to claim 2, wherein said drug comprises an anti-inflammatory agent.

4. An electrically conductive lead according to any of the preceding claims, wherein said electrode member (12) is positioned at the distal end tip of the lead such that the distal end tip of the lead is formed by said porous metal foam material.

5. An electrically conductive lead according to any of the preceding claims, wherein substantially the whole electrode member (12) is formed by said porous metal foam material.

6. An electrically conductive lead according to any of the preceding claims, wherein the material of said electrode member (12) comprises tantalum and/or titanium.

7. An electrically conductive lead according to any of the preceding claims, wherein the pores of said part (26), which is formed of a porous metal foam material, constitute at least 50% of the volume of said part (26).

8. A method of producing a an electrically conductive lead suitable to be implanted in a human or animal body, the method comprising:

providing an electrode member (12) wherein at least a part (26) of said electrode member (12) is formed of a porous metal foam material,

providing other members for forming the lead and assembling the members to form an electrically conductive lead having a proximal end portion designed to be attached to a device, a distal end portion, which comprises said electrode member (12), the electrode member (12) being arranged for emitting and/or sensing electrical signals, and an elongated body extending between said proximal end portion and said distal end portion.

9. A method according to claim 8, comprising the step of arranging a drug, adapted to be released into said human or animal body, in said porous part (26).

10. A method according to claim 9, wherein said drug comprises an anti-inflammatory agent.

11. A method according to any of claims 8-10, comprising the step of arranging said electrode member (12) at the distal end tip of the lead such that the distal end tip of the lead is formed by said porous metal foam material.

12. A method according to any of claims 8-11, wherein substantially the whole electrode member (12) is formed of said porous metal foam material.

13. A method according to any of claims 8-12, wherein the material of said electrode member (12) comprises tantalum and/or titanium.

14. A method according to any of the claims 8-13, wherein said porous metal foam material is formed such the pores constitute at least 50% of the volume of porous metal foam material.

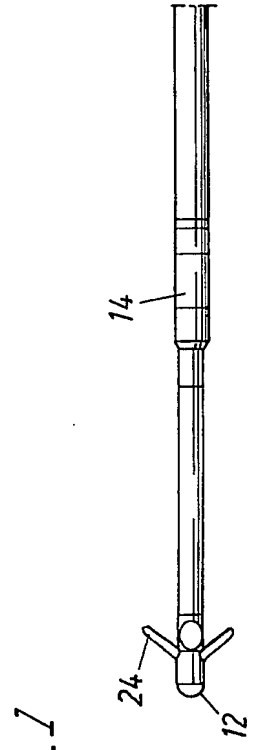


Fig. 1

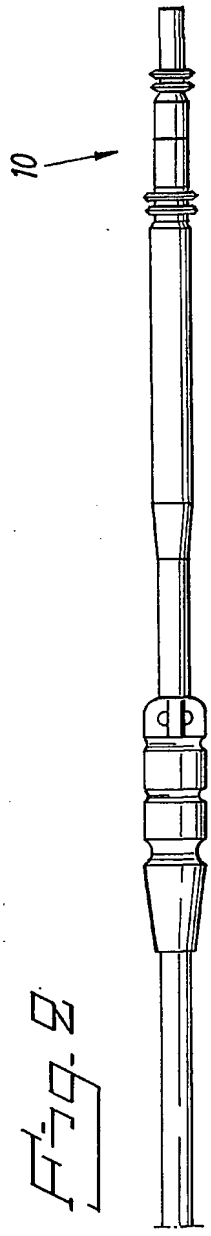


Fig. 2

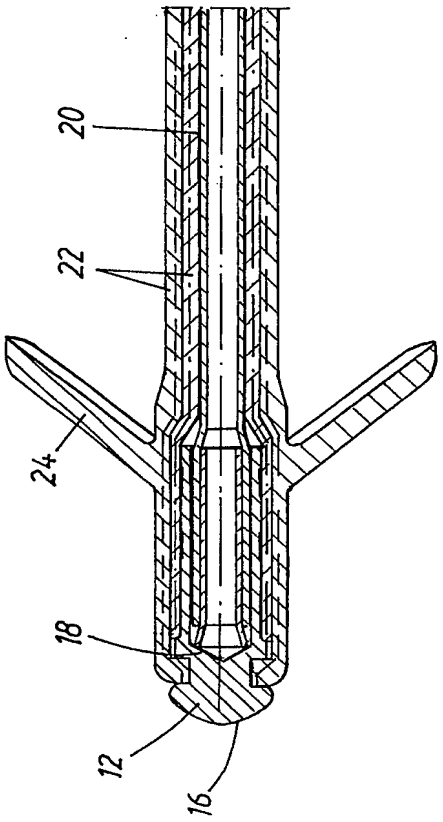


Fig. 3

Fig. 4

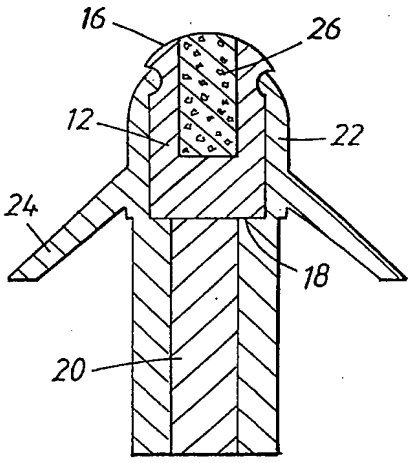
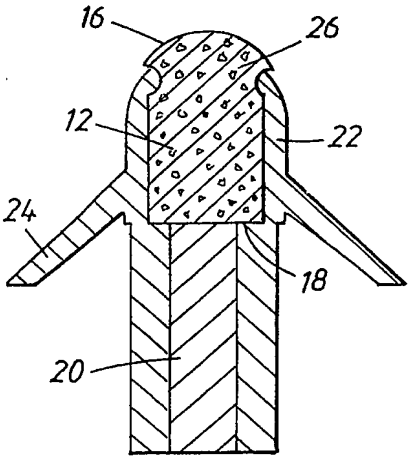


Fig. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/00602

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/05
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4844099 A (M. SKALSKY ET AL), 4 July 1989 (04.07.89)	1-5,8-12
Y		6-7,13-14
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Y	US 5282844 A (K.B. STOKES ET AL), 1 February 1994 (01.02.94), claim 2	13
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Y	US 4819661 A (R.W. HEIL, JR. ET AL), 11 April 1989 (11.04.89), column 5, line 51 - line 65	14
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☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search	Date of mailing of the international search report
7 May 2002	10 -07- 2002
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Christer Wendneius / MRo Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT
Information on patent family members

28/01/02

International application No.
PCT/SE 02/00602

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		FR 2607013 A,B	27/05/88
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